Articles + Publications | September 22, 2025

Will the Supreme Court Give Drug Manufacturers the Skinny on Induced Infringement?

WRITTEN BY

Alan B. Clement | Jeremy Murphy

The Supreme Court may soon address a recent, pivotal case involving the use of "skinny labels" to avoid inducing infringement in pharmaceutical patent infringement cases. The outcome could clarify whether and how generic drug manufacturers can use skinny labels, alone or in conjunction with other advertising or marketing activities, to avoid inducing patent infringement. Skinny labeling is the practice of including only non-patented indications on a drug label (or package insert), while carving out patented indications, in an attempt to avoid inducing infringement on patents covering the carved-out indications.

To date, court rulings have varied. Should the Court elect to hear the issue, its decision could redefine labeling and marketing practices for generic manufacturers and set the legal standard for how a brand manufacturer can claim induced infringement in the presence of a skinny label.

Understanding Skinny Labels

Skinny labeling allows generic manufacturers to make use of the statutorily allowed practice to exclude indications from their drug labels that are covered by method-of-treatment patents listed in the FDA's Orange Book. Because generic companies themselves do not treat patients, the infringement question on method-of-treatment patents typically revolves around whether the generic manufacturer is inducing infringement.

Generics often use skinny labeling to facilitate market entry and mitigate risk of inducing patent infringement claims, arguing that they are not inducing infringement on a patented method of treatment because their labels do not contain the patented indication. However, there is ongoing debate in the courts about the extent to which other communications, statements, or promotions of generic products might lead to induced infringement.

Some of these communications or statements at issue revolve around a generic company's statements that their product is "bioequivalent" or "A/B rated" (which means that a prescription for the brand product can be freely substituted with the generic unless the prescriber writes "Dispense as Written" or "DAW"). But questions remain whether that alone can lead to inducement.

The Case at Hand

In *Amarin Pharma, Inc. v. Hikma Pharm. USA Inc.*, a manufacturer alleged induced infringement related to use of a skinny label for a generic version of its drug, Vascepa®. Vascepa® was originally approved only for treating severe hypertriglyceridemia. Both the Vascepa® and generic labels also originally included a limitation stating that

©2025 Troutman Pepper Locke

use for treating cardiovascular mortality and morbidity had not been determined ("the CV limitation").

When the branded manufacturer subsequently obtained approval for Vascepa® to treat cardiovascular risk, both the brand and the generic removed the CV limitation from the label, and the branded manufacturer listed new patents covering the new indication in the Orange Book. The generic carved out the new indication from its label, but the branded manufacturer filed suit.

The branded manufacturer claimed that the generic's labeling, combined with its marketing and press release statements, including those highlighting bioequivalence of the products, constituted induced infringement. In particular, the branded manufacturer pointed out the following alleged statements as potentially supporting the generic manufacturer's intent to induce infringement:

- Label statement regarding risk factors for people with cardiovascular disease;
- Patient information leaflet stating that medicines may be prescribed for other purposes;
- Removal of the CV limitation from the label;
- Press release that the product was a "generic version" of Vascepa®;
- Press release calling the product "generic Vascepa®";
- Press release quoting total sales of Vascepa,® including sales for the cardiovascular indication;
- Press release describing Vascepa® as "indicated, in part," for treating severe hypertriglyceridemia; and
- Website statement that its product was "AB" rated with a disclaimer that it "is indicated for fewer than all approved indications of the Reference Listed Drug."

The generic manufacturer also issued a final press release upon its official product launch stating that its product was indicated for treating severe hypertriglyceridemia — but that it "is not approved for any other indication for the reference listed drug VASCEPA®."

The district court originally dismissed the induced infringement allegations. However, the U.S. Court of Appeals for the Federal Circuit reversed the ruling, suggesting that at the motion to dismiss stage, the generic's labeling taken in combination with the public statements at least plausibly supported the branded manufacturer's claim.

Potential Industry Impact

The generic manufacturer has petitioned the Court for a writ of certiorari, and the Court has requested input from the solicitor general. As the industry awaits the decision on whether the Court will hear the case, the potential implications for labeling practices, advertising, and the use of skinny labels are significant:

1. Label Statements: The decision could influence how generic products are labeled, and what types of label statements either support or detract from a showing of the intent element of inducing infringement. If the Court's ruling establishes that certain risk-related statements on labels (or in leaflets) can be construed as evidence of intent to induce infringement, generic manufacturers may need to adopt more restrictive labeling and risk-related statement practices in the future.

2. Marketing and Promotion: The decision could also influence whether a generic company can market its product as AB rated, or as "generic to the brand." If the ruling establishes that such marketing claims, even with

disclaimers, imply intent to induce patent infringement, generic companies may need to reassess their promotional language. This may also lead to stricter guidelines on the size and prominence of disclaimers to mitigate legal risks. Generic manufacturers may also need to explicitly state non-equivalence for indications not on the label and take steps to discourage carved-out indications.

3. Communication Practices: The decision could influence how sales data are utilized in communications. If using total sales data of a branded product in press releases is deemed indicative of intent to induce, generic manufacturers may need to adopt more nuanced approaches in their public communications. This could involve a greater emphasis on transparency and specificity regarding which indications are covered by their products.

If the Court decides not to hear the case on skinny labeling, the Federal Circuit reversal could signal to the industry that these practices will be subject to increased scrutiny. Generic manufacturers may need to exercise more vigilance in their statements and advertisements, while branded patent holders will be incentivized to scrutinize those same statements and advertisements for evidence of intent. Additionally, since the case is at the motion to dismiss stage, the case bears watching for a final determination on the inducement issue.

Conclusion

The Court's potential decision on induced infringement could significantly alter generic pharmaceutical labeling and marketing practices in the face of method-of-treatment type patents. If the Court takes up the case, significant light may be shed on what marketing practices do or do not provide evidence of intent sufficient to find induced infringement, despite a generic company carving out a method-of-use patent claiming a label indication.

RELATED INDUSTRIES + PRACTICES

- FDA Regulatory + Risk Management Counseling
- Health Care + Life Sciences
- Health Care + Life Sciences Intellectual Property
- Intellectual Property
- Pharmaceutical + Medical Device Litigation + Counseling

©2025 Troutman Pepper Locke